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In Re: Patent Term Extension
Application for
U.S. Patent No. 7,323,493

MAILED
July 12, 2012
DCPEP-OPLA

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 7,323,493, claims of which cover the human drug product MULTAQ® (dronedarone hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 519 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 5,223,510 based on the regulatory review period for MULTAQ® (dronedarone hydrochloride).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent U.S. Patent No. 7,323,493 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 5,223,510. In the absence of a request for reconsideration, and if U.S. Patent No. 7,323,493 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 519 days in U.S. Patent No. 7,323,493.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 10, 2010 (75 Fed. Reg. 76991). Under 35 U.S.C. § 156(c):

$$\text{Period of Extension} = \text{RRP} - \text{PGRRP} - \text{DD} - \tfrac{1}{2}(\text{TP} - \text{PGTP})^{1}$$

[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on

= 5,076 - 4,557 - 0 - ½ (3,593 - 3,593)
= 519 days (1.4 years)

Since the regulatory review period began August 10, 1995, before the patent issued (January 29, 2008), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 10, 1995 through and including June 10, 2005 is 3593 days (testing phase days), and from June 10, 2005 through and including January 29, 2008 (approval phase days), is 964 days; this total period of 4,557 days is subtracted from the number of days in the regulatory review period according to the FD's determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	7,323,493
Granted:	January 29, 2008
Original Expiration Date[2]:	June 19, 2018
Applicant:	Bernard Abramovici et al.
Owner of Record:	sanofi-aventis
Title:	Solid Pharamceutical Composition Containing Benzofuran Derivatives
Product Trade Name:	MULTAQ® (dronedarone hydrochloride)
Term Extended:	519 days

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which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Expiration Date of Extension: November 20, 2019

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: MULTAQ® (dronedarone hydrochloride)
Docket No.: FDA-2009-E-0039